

REMARKS

A. Request for Reconsideration

Applicants have carefully considered the matters raised by the Examiner in the outstanding Office Action but remain of the opinion that patentable subject matter is present. Applicants respectfully request reconsideration of the Examiner's position based on the amendments made to the claims and the following remarks.

B. The Present Invention

One of the unique aspects of the present Invention is the fact that the contrast medium is prepared without the use of an organic solvent. Because no organic solvent is used in preparing the contrast medium, the contrast medium contains no organic solvent. In order to emphasize this unique aspect of the present Invention, the claims have been amended herein to recite that the contrast medium contains no organic solvent and the method of preparing the contrast medium is done without an organic solvent.

C. Claims Status

Claims 1 through 26 are presented for further prosecution.

Claim 1 has been amended herein to recite that the contrast medium contains no organic solvent. Claim 21 has been amended herein to recite that the vesicle that is produced contains no organic solvent. Support for these amendments can be found, for example, on page 23, line 15- page 24, line 4 of the Specification.

Claim 3 has been amended herein to recite that the liposome is made up of at least 80 % unilamellar vesicles. Support for this amendment can be found, for example, on page 28, lines 7-11.

Respectfully, no new matter has been added by way of this amendment.

C. 112 Rejections

The Examiner has rejected claims 1 and 21 as being unclear as to what amount constitutes substantially no organic solvent. Applicants have amended claims 1 and 21 to remove the word "substantially" in order to clarify that there is no organic solvent in the contrast medium and in the vesicle.

The Examiner also rejected claim 3 as being unclear as how to determine a substantially acceptable amount of unilamellar vesicles. Applicants have amended claim 3 to recite an amount of at least 80 % unilamellar vesicles.

D. Prior Art Rejection

The Examiner has made the following three prior art rejections:

(1) claims 1 and 4-8 are anticipated by Na (U.S. 5,326,552);

(2) claims 1-18 and 21-26 are unpatentable over Mackaness et al. (U.S. 4,192,859) in view of Otake et al. (U.S. 2004/0099976) or Castor (U.S. 5,554,382) and further in view of Na; and

(3) claims 1-16 are unpatentable over Klaveness et al. (U.S. 5,676,928) in view of Otake or Castor and further in view of Na.

At the outset, Applicants note that Na, Mackaness, Otake, Castor and Klaveness each teach the use of organic solvents in preparation of their materials (col. 3, lines 56-63. of Na; col. 3, lines 40-46 of Mackaness; paragraphs 26, 57, 60 and 64 of Otake; col. 3, lines 20-29 of Castor; and col. 8, lines 46-52 of Klaveness).

Na teaches the use of organic solvents in preparation of his materials (col. 3, lines 56-63). In contrast, the present Invention specifically claims that there is no organic solvent in the contrast medium or in the in the preparation. In fact, Applicants have amended claims 1 and 21 to recite that there is no organic solvent in the contrast medium or in the in the preparation. Thus, Na does not teach or suggest the liposome of the present Invention.

The Examiner is reminded of Mr. Ueda's Declarations of December 28, 2006 and April 5, 2007, wherein contrast mediums were made in accordance with the teachings of Mackaness and Klaveness, using an organic solvent. Paragraph 6 of the December 28, 2006 Declaration recited that the contrast mediums contain organic solvent. In Paragraph 7 of the April 5, 2007 Declaration, the amount of solvent in the contrast medium is recited. In light of Mr. Ueda's Declarations, it is respectfully submitted that the teachings of both Mackaness and Klaveness clearly result in the presence of organic solvent both in the preparation process and in the contrast medium which results from the preparation process.

The Examiner will also note that in the secondary references of Otake and Castor, both teach the use of a cosolvent during preparation, see Paragraph 26 of Otake and Column 3, lines 20-29 of Castor. Otake uses cosolvents in each of his embodiments, as recited in Paragraphs 57, 60 and 64. Castor uses cosolvents in each of Examples 1, 2, 4, 5, 6, and 7. Thus, it is respectfully submitted that Mackaness, Otake, Castor and Klaveness would lead one of skill in the art to use an organic solvent in the preparation of the materials. This is contrasted with the present Invention which requires that no organic solvent is used in the preparation and no organic solvent is present in the contrast medium.

With respect to prior art rejection (1), Na had been cited to teach a liposome. However, Applicants respectfully submit that Na does not teach a liposome comprised of vesicles including a water-soluble nonionic iodine compound.

First, Na teaches nanoparticles, not liposomes. Nanoparticles and liposomes are physically different; a nanoparticle is essentially uniform in structure.

Specifically, the nanoparticle of Na is a solid iodine compound in a crystalline form (col. 3, lines 27-30). In contrast, the liposomes of the present Invention are multiphasic, having at least three layers: (1) an outer membrane of the lipid material; (2) a water-containing vesicle; and (3) an iodine compound within the vesicle. Thus, the nanoparticle of Na is not the liposome of the present Invention.

Second, Na does not teach a vesicle with a water phase which contains the water-soluble nonionic iodine compound. Na teaches a high molecular weight surfactant adsorbed on the surface of the nanoparticle and a lipid that is associated with the surfactant (col. 2, lines 37-41). In contrast, the present Invention provides that the vesicle is made of a lipid membrane, not a surfactant. Moreover, the lipid membrane of the vesicle is not directly associated with the water-soluble nonionic iodine compound; rather, the water phase contains the iodine compound. Thus, Na does not teach the liposome of the present Invention.

With respect to prior art rejections (2) and (3), Na does not cure the deficiencies of Mackaness, Otake, Castor

and Klaveness. As discussed above, all of the references cited by the Examiner teach the use of an organic solvent in the preparation of materials. Moreover, Na does not teach a liposome comprised of vesicles including a water-soluble nonionic iodine compound.

Since none of the references cited by the Examiner, taken alone or in combination, teach or suggest the liposome of the present Invention, it is respectfully submitted that the claims presented herein are patentable over the Examiner's rejections.

E. Double Patenting Rejection

Claims 21, 22 and 25 had been provisionally rejected on the basis of non statutory double patenting over claims 1-4, 6 and 8-10 of copending Application 11/180,849; and claims 21, 22 and 25 had been provisionally rejected on non statutory double patenting over claims 1, 5-7, 11, 12, and 14-17 of copending Application 11/187,397.

Given the fact that these are both provisional rejections and that all three applications are currently pending, Applicants propose to wait until an indication of

allowable subject matter before filing a Terminal Disclaimer.

G. Conclusion

In view of the foregoing and the enclosed, it is submitted that the Application is in condition for allowance and such action is respectfully requested. If it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to Deposit Account #02-2275.

Respectfully submitted,

LUCAS & MERCANTI, LLP

By:



Donald C. Lucas, Reg. #31,275
(Attorney for Applicants)
475 Park Avenue South
New York, New York 10016
Tel. # (212) 661-8000
Fax # (212) 661-8002

DCL/cmj/mr